

Claims 1, 3, 9-11 were rejected under 35 U.S.C. § 102(b) as being clearly anticipated by U.S. Patent No. 5,591,138 to Vaillancourt et al. Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,591,138 to Vaillancourt et al. Claims 4-8 and 12-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,591,138 to Vaillancourt as applied to claim 1, and further in view of U.S. Patent No. 6,287,283 to Ljunggreen et al.

Vaillancourt et al. teach a needle protection device that serves to prevent accidental needle sticks when one person is administering an injection to another person. In such a situation, the phobia associated with the penetration of a needle into a patient's tissue can be avoided or minimized by the patient simply averting their view during the injection.

Conversely, the presently claimed invention is directed to an injection device that is used for the self-administration of an injection. As such, the patient must view the process and the device. Furthermore, the patient must be assured of achieving adequate needle penetration while still avoiding viewing of the actual penetration, for those patient's suffering from a needle phobia.

Thus, the presently claimed invention differs from the device taught by Vaillancourt et al. The claimed device includes a needle protection sleeve that is moveable within a receiving sleeve. A positive indication is provided when the needle protection sleeve reaches the distal position; a position that indicates the appropriate needle depth has been achieved. In this manner some indication is given to the patient that the end result has been reached; however, all other visual stimuli that would be negatively perceived by a patient with a needle phobia have been dramatically reduced or eliminated. That is, by retracting the needle protection sleeve within the receiving sleeve, the patient has no visual indication of the actual depth of penetration of the needle. When a needle protector is positioned on and moveable about the outside, exposed portion of a housing – as is the case with the Vaillancourt et al. embodiment that arguably includes an indicator as illustrated in Figs. 13-14 - the patient can readily discern the relative position (or depth) of the needle by monitoring the rear edge of the needle protector. Thus, as the needle protector moves, so moves the actual needle into the patient's tissue. For those patient's suffering from a needle phobia, this makes the self-administration of an injection very difficult, if not impossible.

As the Vaillancourt et al. reference fails to teach an injection device having a needle protection sleeve moveable within a receiving sleeve and having an indicator to indicate that the needle protection sleeve has reached a distal position it cannot anticipate claims 1 and 11. Thus, Applicant respectfully asserts that these claims are allowable. As the remaining claims depend therefrom, those claims are allowable for at least the same reasons.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Marked-up Version Showing Changes.**"

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

Respectfully submitted,

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MARKED-UP VERSION SHOWING CHANGES**IN THE ABSTRACT**

An apparatus for subcutaneous administration of an injectable product, including a housing, a container for the product to be injected, an injection needle and a needle protection sleeve surrounding the injection needle, [whereinhe] wherein the apparatus also includes an indicator to tell a user when the needle protection sleeve has attained its maximum distal position.

IN THE CLAIMS

1. (Amended) An apparatus for subcutaneous self-administration of an injectable product into a patient comprising:

- a) a housing;
- b) a container for said product, said container being accommodated by said housing;
- c) an injection needle connected to said container and protruding beyond said housing; and
- d) a needle protection sleeve, surrounding said injection needle and preventing the patient from viewing the needle entering and penetrating tissue and for preventing the patient from gauging a depth of penetration, said needle protection sleeve reciprocatingly shiftable between a proximal position and a distal position, wherein in said distal position, said injection needle protrudes beyond said needle protection sleeve and the needle protection sleeve is received within a receiving sleeve coupled with the housing and disposed concentrically around the needle protection sleeve so that movement of the needle protection sleeve within the receiving sleeve is obscured from view so that the patient is unable to gauge the depth of penetration based on movement of the needle protection sleeve within the receiving sleeve and in said proximal position, said injection needle does not protrude beyond said needle protection sleeve; and
- e) an indicator which indicates to a user of said apparatus that said needle protection sleeve is in [its] the distal position.

9. (Amended) The apparatus as set forth in claim 1, wherein said indicator outputs a first signal when said needle protection sleeve has attained [its] the distal position and outputs another signal as long as said needle protection sleeve has still to attain [its] the distal position.

11. (Amended) An apparatus for subcutaneous self-administration of an injectable product by a patient comprising:

a housing;

a receiving sleeve coupled with the housing;

an injection needle protruding beyond said housing;

a needle protection sleeve generally surrounding said injection needle, said needle protection sleeve connected to said housing and slidable between a proximal position and a distal position, wherein, in said distal position said injection needle protrudes beyond said needle protection sleeve and the needle protection sleeve is disposed within an interior of the receiving sleeve so that the patient cannot view the needle entering and penetrating tissue and the patient cannot gauge the relative position of the needle by monitoring the relative movement of a rear portion of the needle protection sleeve and in said proximal position, said injection needle does not protrude beyond said needle protection sleeve; and
an indicator which indicates to a user of the apparatus that the needle protection sleeve is in [its] the distal position.

12. (Amended) The apparatus according to claim 11, wherein said indicator provides a first signal when said needle protection sleeve is in [its] the distal position and a second signal as long as said needle protection sleeve is not in [its] the distal position.

14. (Amended) The apparatus according to claim 13, wherein said indicator provides a first signal when said needle protection sleeve is in [its] the distal position and a second signal as long as said needle protection sleeve is not in [its] the distal position.